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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,221	02/16/2001	Doris Hubler	JENA 3	7076

23599 7590 12/05/2001

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EXAMINER

NGUYEN, HELEN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 12/05/2001

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/719,221

Applicant(s)

HUBLER ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 7-17 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 7-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The amendment of paper no. 11, filed September 17, 2001, is acknowledged.

Claims 2-4 are amended.

Claims 13-17 are newly added.

Claims 1-4, and 12 -17 are pending and presenting for examination.

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In view of the amendment of paper no. 11, filed September 17, 2001, the rejection of claims 1-4 and 12 of record under 35 U.S.C. 102 (b) as anticipated by Cohen (WO 91/00095), is hereby withdrawn. However, new grounds of rejection are applied as follows:

#### ***Specification objection***

*not* ✓ The disclosure is objected to because of the following informalities: on page 5, last paragraph of the specification, the term "i.m." is vague because of acronym. "intramuscular" is suggested.

Appropriate correction is required.

#### ***Claim rejection***

❖ The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph,

because the specification, while being enabling for a range of 20  $\mu$ g - 20

mg for gestagen, does not reasonably provide enablement for the same

range for any secondary compound. The specification does not enable any

*gestagen*  
*vs*  
*Species?* ~~person skilled in the art to which it pertains, or with which it is most nearly~~

connected, to make/use the invention commensurate in scope with these

claims. In the specification on page 6, lines 11-12, Applicants disclose the

range only for gestagen.

❖ The following is a quotation of **35 U.S.C. 103(a)** which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5/15/02  
Wjm  
3, except cl. 3  
Claims 1-2, 4, and 12-17 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Hesch et al. (US Patent No. 5,795,883) in view of Neri (US Patent No. 3,423,507), Rubin (US Patent No. 5,059,603), and further in view of Riley et al. (Facts and Comparisons).

Hesch et al. disclose that it is well-known in the art that androgens such as testosterone are useful in methods of treating androgen deficiency in man (column 1, lines 10-16). Such a deficiency is known to cause benign enlargements of the prostate (column 1, lines 46-54)

Hesch et al. do not disclose gestagens.

Neri discloses that gestagens, particularly cyproterone, are useful in methods of treating benign prostatic hypertrophy (title, abstract, column 1, lines 21-25 and claim 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add gestagens to the androgens of Hesch et al. to further enhance the treatment of benign prostatic hypertrophy.

As to the particular claimed synthetic androgens, Rubin teaches that such androgens, including the claimed methyl testosterone, are well-known in the art for treating androgen deficiency (column 2, lines 59-62).

See In re Kerkhoven 205 USPQ 1069. The combination of agents, each of which is known to be useful individually for the same purpose, into a single composition useful for the very same purpose, e.g. *treatment of benign prostatic hypertrophy*, is prima facie obvious. At least additive therapeutic effects would be reasonably expected.

As to the claimed ranges of androgens and gestagens dosages, it is ~~within the skill in the art to select optimal parameters such as ratios, ranges~~ of doses or weight percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 19880). Therefore, the ratios, ranges of doses or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

As to the claimed dosage forms of androgens and gestagens, Riley et al. disclose varieties of dosage forms for androgens and gestagens. It would have been obvious to one having ordinary skill in the art to choose a particular dosage form appropriate for the patient under treatment.

Claims 1- 4, and 12-17 are rejected.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes

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that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35

~~U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).~~

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen  
Patent Examiner

November 27, 2001



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EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500